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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,301	08/10/2001	Craig A. Rosen	PA106P1	2139

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	10

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,301	ROSEN ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *24-33* is/are allowed.

6)☒ Claim(s) *34-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The Art Unit location of your application, and the examiner to whom the case has been docketed in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Zachariah Lucas in Art Unit 1648.

Election/Restrictions

2. Applicant's election with traverse of Group III, wherein the protein is that of SEQ ID NO: 966, in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the Examiner has not established undue burden in the examination of the separate inventions identified in the restriction requirement. The Applicant argues that a search for the elected invention would provide pertinent information with regards to the non-elected inventions. This is not found persuasive because, even assuming that the search for the elected invention did provide such pertinent information, additional searches not coextensive with that required for the elected invention would still be required for the additional inventions. Thus, there would be an undue burden on the office in searching for all of the inventions identified in the originally filed claims.

The requirement is still deemed proper and is therefore made FINAL.

3. Currently, claims 24-38 are pending and under consideration.

4. Applicant's attention is directed to the section entitled INTERFERENCE in this action, which follows those sections of the action substantively relating to the prosecution of the currently pending claims.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on June 30, 2003, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Specification

6. The disclosure is objected to because of the following informalities: on page 41 of the application, SEQ ID NO: 208 is indicated as encoding the protein prostasin. Further, the coding region of SEQ ID NO: 208 appears to be similar to the sequence disclosed in the art as encoding prostasin. Compare, SEQ ID NO: 208 with SEQ ID NO: 1 of U.S. 2002/0090625 (showing difference between the sequence known in the art and SEQ ID NO: 208 at bases 315, and bases 809-812.). However, whereas the application appears to indicate that SEQ ID NO: 208 encodes prostasin, on page 304-305, the specification also appears to indicate that the sequence referred to as Sequence/Contig ID 828897 (identified as SEQ ID NO: 208 on page 41) includes the epitope of SEQ ID NO: 1050. This sequence does not appear to be a prostasin sequence.

Appropriate correction is required.

Claim Objections

7. Claim 34 is objected to because of the following informalities: in line two of the claim, it reads "wherein said fragment at least 30 contiguous amino acid residues in length." It is suggested that the term - -is- - should be inserted between the terms "fragment" and "at least." Appropriate correction is required.

8. Claim 36 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 36 describes the polypeptide of claim 34, wherein said polypeptide comprises a heterologous polypeptide sequence. However, claim 34 reads on a polypeptide consisting of a fragment of SEQ ID NO: 966 that is at least 30 residues in length. Because claim 34 uses the language "consisting of a fragment of SEQ ID NO: 966," the claim excludes polypeptides containing sequences other than those of SEQ ID NO: 966. Thus, by including the additional limitation of having a heterologous sequence in claim 36, the claim is reading on material excluded by the language of claim 34, and is therefore broader in scope in comparison to claim 34. Because claim 36 reads on a broader scope of inventions from those of claim 34, the claim is not properly dependant.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 34-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides that are capable of generating antibodies that specifically bind to a polypeptide consisting of amino acid residues 1 to 131 of SEQ ID NO: 966, does not reasonably provide enablement for any fragment of the sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The Applicant has indicated that polypeptides of residues 1 to 131 of SEQ ID NO: 966 would be useful in the diagnosis of cancer of the breast, ovary, or pancreas. Thus, the Applicant has provided a use for fragments that are capable of generating antibodies that can be used to detect the full-length protein. However, the Applicant has not provided any other function or use for the claimed polypeptides. Because it is not clear that any fragment of SEQ ID NO: 966 would be capable of generating such antibodies, and because no other uses for such fragments have been disclosed, the Applicant is not enabled for any fragment of the polypeptide. It is suggested that the Applicant insert the functional language from claim 29 into the language of the rejected claims.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 34-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims have been described above. As indicated above, although claims 34 and 35 read on polypeptide "consisting of a fragment" of SEQ ID NO: 966, and would therefore

usually be read as excluding sequences comprising heterologous sequence to SEQ ID NO: 966, the Applicant has also included claim 36 further limiting claim 34 to embodiments wherein the polypeptide "comprises a heterologous polypeptide sequence." It is therefore unclear what is meant by the language "consisting of" in claim 34.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 34-38 are rejected under 35 U.S.C. 103(a) as obvious over the teachings of Williams et al., U.S. Publication 2002/0076735. For the purposes of this rejection, the claims are interpreted as reading on isolated polypeptides comprising a fragment of SEQ ID NO: 966 that is at least 30, or 50, amino residues in length.

Williams teaches a number of polynucleotides whose expression has been associated with the diagnosis of cancer. Among the polynucleotides disclosed is that of SEQ ID NO: 1 (in that reference) which shares identity with at least 50 codons of the coding sequence for SEQ ID NO: 966 (i.e. SEQ ID NO: 124) in the present application. The reference teaches methods of using antibodies to the polypeptides encoded by the disclosed polynucleotides for the diagnosis of cancer. See, pages 13-15 ; esp., page 15, paragraph 0137. The reference teaches that these antibodies are made through the expression of the encoded polypeptides, and use of the

polypeptides for the production of antibodies. Pages 12-13. Thus, the reference teaches a polynucleotide encoding fragments of SEQ ID NO: 966, and the expression and use of those polypeptides. It is further noted that expression of the entire sequence of SEQ ID NO: 1 in the publication would result in a polypeptide comprising a heterologous sequence. The reference therefore renders all of the indicated claims obvious.

It is noted that the Williams reference relies on provisional application 60/101,900 for priority. A copy of the provisional application is being provided.

Interference

15. The following allowable claim is suggested for the purpose of an interference:

A method of determining whether a woman is at increased risk of having ovarian cancer comprising:

(a) obtaining a test sample of plasma or serum from said woman;

(b) determining the concentration of prostasin in said test sample;

(c) comparing the results of the determination of step (b) with the results obtained using a control sample; and

(d) concluding that said woman is at increased risk of having ovarian cancer if the concentration of prostasin in said test sample is significantly higher that the concentration in said control sample.

A comparison of the sequence disclosed as prostasin in application 09/948094 (See, SEQ ID NO: 2 of U.S. PG Pub 2002/0090625) with SEQ ID NO: 1050 of the present application indicates that the protein of Sequence/Contig ID 828897 of the present application is the prostasin protein.

The suggested claim must be copied exactly, although other claims may be proposed under 37 CFR 1.605(a).

Applicant should make the suggested claim within ONE MONTH or THIRTY DAYS from the mailing date of this letter, whichever is longer. Failure to do so will be considered a disclaimer of the subject matter of this claim under the provisions of 37 CFR 1.605(a). THE PROVISIONS OF 37 CFR 1.136(a) DO NOT APPLY TO THIS TIME PERIOD.

Although the Applicant has cancelled the claims that would be considered unpatentable over this suggested claim, previously pending claim 19 would have been considered unpatentable over this suggested claim.

Conclusion

16. Claims 34-36 are rejected. Claims 24-33 appear to be free of the prior art.

17. The following prior art reference is made of record and is considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

> Mok et al., U.S. Pub. 2002/00900625. This reference teaches a method of diagnosing a cancer comprising the detection of a protein disclosed as SEQ ID NO: 208 (prostasin) in the present application.

Genebank accession AI288765 (of record in the IDS) appears to be a nucleic acid encoding residues 22-131 of SEQ ID NO: 966. However, the reference does not teach the polypeptide encoded thereby, or a reason for making such a polypeptide.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

JAMES HOUSEL 2/23/04
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